JUL 17 2002

K021280 page 1 of 2

510(k) SUMMARY
for the Inion Hexalon™ Biodegradable ACL/PCL Screw

MANUFACTURER
Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere

Contact Person:
Hanna Marttila
Regulatory Affairs Manager
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hanna.marttila@inion.fi

DEVICE NAME
Trade name: Inion Hexalon™ Biodegradable ACL/PCL Screw
Common/Usual Name: Biodegradable Interference Screw
Classification Name: Bone Fixation Screw

ESTABLISHMENT REGISTRATION NUMBER
9710629

DEVICE CLASSIFICATION AND PRODUCT CODE
Classification panel: Orthopedic
Regulatory Class: Class II
21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener, 87-HWC

PREDICATE DEVICES
Linvatec Corporation; BioScrew® Absorbable Interference Screw (K973758)
Arthrex, Inc.; The Arthrex Bio-Interference Screw (K971358)
Biomet Inc.; Arthrotek Interference Screw (K982497)
Sulzer Orthopedics Inc.; Sysorb Interference Screw (K983592)

Date:19.4.2002
Status: Final

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion Hexalon™ Biodegradable ACL/PCL Screw is intended for use in anterior/posterior cruciate ligament (ACL/PCL) reconstruction procedures. The Inion Hexalon™ Biodegradable ACL/PCL Screw is indicated for fixation of bone-patellar tendon-bone graft to the femoral/tibial bone drill hole in the anterior cruciate ligament reconstruction, fixation of the soft tissue graft to the femoral/tibial bone drill hole in the anterior cruciate ligament (ACL) reconstruction and reconstruction of posterior cruciate ligament (PCL)

The Inion Hexalon™ Biodegradable ACL/PCL Screw is made of resorbable polylactic acid / trimethylenecarbonate copolymers and it is provided in the various lengths and diameters typical of the other marketed devices. The Inion Hexalon™ Biodegradable ACL/PCL Screw is offered both undyed and coloured for better visualization during surgical operation. Colour additive used for dying the device is FDA approved colourant: D&C Green No.6, in accordance with the Title 21 CFR 74.3206. The Inion Hexalon™ Biodegradable ACL/PCL Screws gradually lose their strength during 18-36 weeks. Bioresorption takes place within two to four years.

EQUIVALENCE TO MARKETED PRODUCTS

The Inion Hexalon™ Biodegradable ACL/PCL Screw is substantially equivalent to the biodegradable screws, intended for ACL and PCL reconstruction procedures, which have received 510(k) clearance. The Inion Hexalon™ Biodegradable ACL/PCL Screw and BioScrew® Absorbable Interference Screw (K973758), The Arthrex Bio-Interference Screw (K971358), Arthrotek Interference Screw (K982497) and Sysorb Interference screw (K983592) have the same intended use and principles of operation and very similar design characteristics. Mechanical testing demonstrates that the device is substantially equivalent to the predicate. The differences between the Inion Hexalon™ Biodegradable ACL/PCL Screw and these predicate devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

Ms. Hanna Marttila
Regulatory Affairs Manager
Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere
Finland

Re: K021280
Trade/Device Name: Inion Hexalon™ Biodegradable ACL/PCL Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 19, 2002
Received: April 22, 2002

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Applicant: Inion Ltd.
510(k) Number: K021280
Device Name: Inion Hexalon™ Biodegradable ACL/PCL Screw

Indications:

The Inion Hexalon™ Biodegradable ACL/PCL Screw is intended to be used for interference fixation in anterior and posterior cruciate ligament reconstruction using bone-tendon-bone or soft tissue grafts.

Contraindications:

1. Insufficient quality or quantity of bone for interference screw attachment
2. Active or potential infection
3. Patient conditions including limited blood supply, chronic disease which causes insufficient quality of bone, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse)

Prescription use Yes Over the Counter use No

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021280

Date: 17.4.2002
Status: Final